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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/07/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/277,401

Applicant(s)

JAYE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,10,11,13-16,19-23,40,41,43-47,49-53,55-59 and 63-95 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,66-72,74-92 and 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,7,8,10,13-16,19-23,40,41,43-47,49-53,55-59,63-65,73,93 and 94.

DETAILED ACTION

Application Status

1. In response to the previous Office action (Paper No. 9 mailed on August 14, 2001), Applicants filed a response and amendment on January 3, 2002 (Paper No. 10) and a supplemental response on February 26, 2002 (Paper No. 11). Said response amended Claims 20 and 80; said supplemental response cancelled Claims 24, 25, 28-32, 34, 35, 37, and 39 and added new Claims 85-95. Claims 1, 7, 8, 10, 11, 13-16, 19-23, 40-41, 43-47, 49-53, 55-59, and 63-95 are pending in the instant application.

Election

2. Claims 1, 7, 8, 10, 11, 13-16, 19-23, 40, 41, 43-47, 49-53, 55-59, and 63-95 are pending in the instant application. In Paper No. 7, a 29-way restriction requirement was set forth by the Examiner. In Paper No. 8, Applicants elected Group VIII with traverse. Applicants' arguments will be addressed here.

The traversal is on the grounds that all human LIPG polypeptides should be examined together since the largest sequence, SEQ ID NO:8, contains the two subsequences, SEQ ID NOs: 6 and 10. The Examiner agrees. Claims 20, 66-72, 74-92, and 95 will be examined to the extent that they read on the elected group drawn to human LIPG polypeptides (Claims 73, 93, and 94 are specific for rabbit sequences). See objections to non-elected subject matter below.

Claims 1, 7, 8, 10, 11, 13-16, 19-23, 40-41, 43-47, 49-53, 55-59, and 63-95 are pending in the instant application. Claims 1, 7, 8, 10, 11, 13-16, 19, 21-23, 40-41, 43-47, 49-53, 55-59,

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63-65, 73, 93, and 94 are withdrawn from further consideration as non-elected inventions.

Claims 20, 66-72, 74-92, and 95 will be examined herein.

Priority

3. The instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/032,254 and 60/032,783 filed on December 6, 1996 and U.S. non-Provisional Application No. 08/985,492 filed on December 5, 1997 as requested in the declaration and the first lines of the specification. The instant application is a continuation-in-part of 08/985,492.

Information Disclosure Statement

4. As previously noted, the information disclosure statement (Paper No. 3) filed by Applicants on July 18, 2000 has been reviewed.

Drawings

5. The drawings are considered informal for the reasons detailed in the attached copy of PTO Form 948. Appropriate correction is required prior to allowance.

Withdrawn – Claim Objections

6. Previous objection to Claim 80 for a misspelling is withdrawn by virtue of Applicants' amendment.

Withdrawn – Claim Rejections 35 U.S.C. § 112, second paragraph

7. Previous rejection of Claims 20, 66-72, and 74-84 under 35 U.S.C. § 112, second paragraph for the clarity of the word “pharmaceutical composition” or the pharmaceutical use is withdrawn by virtue of Applicants’ amendment removing “pharmaceutical” from Claim 20.

8. Previous rejection of Claim 80 under 35 U.S.C. § 112, second paragraph for the clarity of the word “biologically-compatible solution” is withdrawn by virtue of Applicants’ amendment to Claim 80.

Maintained – Claim Rejections 35 U.S.C. § 112, second paragraph

9. Previous rejection of Claims 20, 66-72, and 74-84 under 35 U.S.C. § 112, second paragraph for the abbreviation “LIPG” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive.

Applicants argue that the term “LIPG polypeptide” is clearly defined in the specification, particularly on page 30, lines 4-10. The Examiner disagrees. Firstly, the rejection was based on the abbreviation that is undefined upon its first appearance. Upon careful inspection, the term “LIPG” seems to characterize (name) a genus of polypeptides having lipase activity and which lower the level of HDL cholesterol and apolipoprotein AI (see specification, pages 1-2). However, the metes and bounds of the term “LIPG polypeptide” remain unclear. In the specification on pages 29-30, LIPG polypeptide is described as generically describing both LIGN (including SEQ ID NO:6) and LLGXL (including SEQ ID NO:8). Since LIPG polypeptides include, but are not limited to SEQ ID NOs: 6 and 8, and since no particular

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biological activity (enzymatic, immunological, etc.) is defined, the metes and bounds of the term “LIPG polypeptide” are wholly unclear.

Withdrawn – Claim Rejections 35 U.S.C. § 112, first paragraph

10. Previous rejection of Claims 20, 66-72 and 77-84 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants’ arguments. The rejection was based on the fact that one of skill in the art would be unable to make *any* LIPG polypeptide.

Applicants argue that one of skill in the art can utilize SEQ ID NO:7 to make and use other LIPG polypeptides. The Examiner agrees.

11. Previous rejection of Claims 66-68 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicants’ arguments. Applicants have argued that it is well within the capabilities of one of skill in art to screen for such enhancers as required in the claimed compositions. The Examiner agrees.

12. Previous rejection of Claim 74-76 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants’ arguments. Applicants have argued that it is well within the capabilities of one of skill in art to produce variants of known polypeptide sequences. The Examiner agrees.

Withdrawn – Claim Rejections – 35 U.S.C. § 102

13. Previous rejection of Claims 66-68 and 72 under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* is withdrawn by virtue of the Examiner’s reconsideration. Claims 66-68 require an enhancer of activity to be present in the composition of the polypeptide; Cooper *et al.* teach

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no such enhancer. Moreover, the polypeptide of Cooper *et al.* is not human in origin as required by Claim 72.

Maintained – Claim Rejections – 35 U.S.C. § 102

14. Previous rejection of Claims 20, 69-71 and 74-76 under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the lipase polypeptide taught by Cooper *et al.* does not fall into the metes and bounds of an LIPG polypeptide as described on page 30 of the specification. The Examiner disagrees. On page 30, line 8, the specification clearly recites "derivatives" and "mutants" which retain biological activity. The chicken polypeptide taught by Cooper *et al.* has lipase activity (see abstract), thus, retaining a biological activity of the disclosed LIPG polypeptides. Moreover, any polypeptide sequence can be considered a derivative or mutant of the disclosed sequences since these terms have no definite structure associated with them. Additionally, for Claims 74-76, the chicken polypeptide can be considered as "variant" or "fragment" of any of SEQ ID NOs: 6, 8, or 10 since the term variant has no definite structural limitation.

NEW REJECTIONS

Compliance with the Sequence Rules

15. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821

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through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

- a) In Figure 6 and its description on page 21, one DNA sequence and four protein sequences are not clearly defined with SEQ ID NOs.
- b) In Figure 10 and its description on page 22, the full-length protein sequence is not identified by SEQ ID NO.
- c) In Figure 13 and its description on page 23, the DNA sequence LLG7742A is not identified by SEQ ID NO.
- d) On page 104, three DNA primers are disclosed without benefit of SEQ ID NOs.
- e) On page 105, three DNA primers are disclosed without benefit of SEQ ID NOs.
- f) On page 105, a 17-mer peptide is disclosed without benefit of a SEQ ID NO.
- g) On page 107, two DNA primers are disclosed without benefit of SEQ ID NOs.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

16. The specification is objected to for not defining the abbreviations used in the figures. In the description of Figure 6 on page 21, EL, LPL, HL, and PL are not defined. They are defined later on page 83. The clarity of the description of the figures requires these definitions to be present in the description on page 21. Appropriate amendment is required.

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17. The specification is objected to for being confusing in its description of Figure 14 on page 96, lines 24-27. This citation on page 96 describes Figure 14 as having sequence, which is not the case. Appropriate amendment is required.

18. The specification is objected to for being confusing about the origin of the LIPG protein sequences. Particularly, it is difficult to discern which SEQ ID NOs related to human and rabbit sequences. Clear identification of SEQ ID NOs and origin of the polypeptides, preferably in the figures, is required. Moreover, the relationship between SEQ ID NOs: 6, 8, and 10 is not clear. An added sentence to the specification concerning SEQ ID NO:8 as the full-length, 500 residue sequence and SEQ ID NO:6 being a fragment of residues 1-354 and SEQ ID NO:10 being a fragment of residues 1-345 would be helpful in enhancing the clarity of the specification.

19. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter. It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species of LIPG polypeptide, human and rabbit, for completeness.

Claim Objections

20. Claims 20, 66-71, 77-85, 87, 92, and 95 are objected to for containing non-elected subject matter. The instant claims will be examined as if the non-elected subject has been cancelled from the claims.

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21. Claims 69, 70, and 92 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In Claims 69 and 92, the limitation of being a “recombinant” polypeptide, i.e., one produced by recombinant technology, does not further limit the polypeptide because the product (polypeptide) has a particular structure independent of the means of producing it. The same argument is set forth for Claim 70 and “synthetic” polypeptides.

22. Claim 72 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 72 does not further limit the elected subject matter of Claim 20.

23. Claim 95 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A fragment of a full-length polypeptide, as in Claim 95, has less limitation than the requirement of having the full-length protein. Thus, Claim 95 does not further limit the subject matter of Claim 85.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

24. Claims 66-68 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases “enhancing the enzymatic activity” or “enhances the enzymatic reaction” are unclear. Enzymes are “active” on a variety of levels including substrate binding, maximal turnover rate, and turnover rate at biological concentrations. The instant claims, in view of the specification, are unclear as to what activity is enhanced and what constitutes enhancement. Is it faster? Is it better binding? Is it more efficient at low substrate concentrations? The metes and bounds of the terms are unclear. Appropriate clarification is required.

25. Claims 67-68 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The abbreviation “apo” appears in Claims 67 and 68 without definition. Appropriate clarification is required. The Examiner suggests deleting “apo” in Claim 67 and substituting therefor ---apolipoprotein (apo)--- for clarity.

26. Claims 85-92 and 95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the term “LIPG polypeptide” are

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unclear as maintained above for Claims 20, 66-72, and 74-84. Appropriate clarification is required.

27. Claims 85-92 and 95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 85, the phrase “**the** LIPG gene” (emphasis added) is unclear. The article “the” indicates a single sequence. As set forth above, the definition of LIPG polypeptides and their encoding genes is unclear. The direction to a single LIPG gene renders the claims even more confusing. Appropriate clarification is required.

28. Claims 85, 87-92 and 95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 85, the phrase “a 39 kD catalytic domain of the triacylglycerol lipase family” is unclear. The metes and bounds of the domain are ill-defined in the specification. Appropriate clarification is required.

29. Claims 90 and 91 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a polypeptide having the same amino acid sequence (SEQ ID NO:8) can produce different bands on a 10% SDS-PAGE gel. If the smaller apparent molecular protein (Claim 90) is a truncated version, then its sequence is not SEQ ID NO:8. If the smaller protein is not truncated, then the different MW's are wholly unclear.

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Claims 90 and 91 appear to be drawn to the same subject matter – that is SEQ ID NO:8.

Appropriate clarification is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

30. Claims 20, 66-72, 77-85, 88, 92 and 95 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 is drawn to a polypeptide that is claimed solely by name without any definite functional or structural limitations. Claim 85 is drawn to a polypeptide that is claimed by limited structural and functional limitations.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could

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predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification describes a single species of the claimed (and elected) genus, that is human SEQ ID NO:8 – the full-length protein. SEQ ID NOs: 6 and 10 are only truncations of the same sequence. No identification of common characteristics is claimed. Particularly, no definite structure, such as relatedness to SEQ ID NO:8, is listed as a claim limitation. No enzymatic function is listed as a claim limitation. Thus, one of skill in the art would be able to predict other members of the genus based on the disclosure. The Examiner suggests the inclusion of definite structural (relatedness to SEQ ID NO:8) and functional (having lipase activity) in the claims.

31. Claims 74-76 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to polypeptides without definite structure. The optional “variant” polypeptide removes any requirement of relatedness to SEQ ID NOs: 6, 8, or 10. The optional “fragment” allows for small polypeptides with no functional limitations. Thus, the above comments for the written description rejection of Claims 20, 66-72, 77-84, 85, 88, and 92 are reiterated here.

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32. Claim 87 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claim is drawn to a polypeptide having phospholipase A activity without any definite structure. As noted in the above comments for the written description rejection of Claims 20, 66-72, 77-84, 85, 88, 92, structure as related to a function is required for adequate written description of a genus of polypeptides. Thus, the above comments for the written description rejection of Claims 20, 66-72, 77-84, 85, 88, and 92 are reiterated here.

33. Claims 66-68 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Although the genus of enhancers of lipase activity is discussed in the specification, there is no evidence that any representative species of such a large and varied genus was in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. The specification does not disclose any representative species of any of the recited classes of possible enhancers, with or without identifying characteristics. Therefore, Claims 66-

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68 fails to satisfy the written description requirement. The Examiner suggests the instant product claims be amended to method claims for identifying enhancers as described in the specification.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

34. Claims 20, 69-71, 74-84 and 95 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* (Avian adipose lipoprotein lipase: cDNA sequence and reciprocal regulation of mRNA levels in adipose and heart. *Biochim. Biophys. Acta* (1989) 1008:92-101) as evidenced by Gershenwald *et al.* (Monoclonal antibodies to avian lipoprotein lipase. Purification of the enzyme by immunoaffinity chromatography. *Biochim. Biophys. Acta* (1985) 836:286-295). The instant claims are drawn to polypeptide compositions comprising a lipase and buffers, including stabilizers and preservatives. The instant claims are also drawn to fragments of SEQ ID NO:10. Claims 20, 69-71 and 74-76 are also rejected above by a GenBank Cooper *et al.* reference; these are parallel rejections.

Cooper *et al.* teach as previously described. Briefly, Cooper *et al.* teach a purified lipoprotein lipase enzyme (see page 94, left column) whose sequence is about 50% identical to SEQ ID NO:10 (see previously attached alignment). The buffers taught by Cooper *et al.* include phosphate, NaCl, and EDTA (see Gershenwald *et al.*). The sequence of Cooper *et al.* from

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residues 197-214 is identical to SEQ ID N:10 from residues 207-224; this is an 18-mer fragment which is large enough to induce an immune response.

Summary of Issues

35. The following is a summary of issued pending in the instant Application that require Applicants' attention:

- a) The drawings are informal.
- b) The specification does not fully comply with the sequence rules.
- c) The specification stands objected to for not defining the abbreviations used in the figures.
- d) The specification stands objected to for being confusing in its description of Figure 14 on page 96, lines 24-27.
- e) The specification stands objected to for being confusing about the origin of the LIPG protein sequences.
- f) The Abstract stands objected to.
- g) Claims 20, 66-71, 77-85, 87, 92, and 95 stand objected to for containing non-elected subject matter.
- h) Claims 69, 70, 72, 92, and 95 stand objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit.
- i) Claims 20, 66-72, and 74-92 stand rejected under 35 U.S.C. § 112, second paragraph for the term "LIPG".

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- j) Claims 66-68 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrases “enhancing the enzymatic activity” or “enhances the enzymatic reaction”.
- k) Claims 67-68 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation “apo”.
- l) Claims 85-92 and 95 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “**the** LIPG gene”.
- m) Claims 85, 87-92 and 95 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “a 39 kD catalytic domain of the triacylglycerol lipase family”.
- n) Claims 90 and 91 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for being drawn to the same SEQ ID NO but having different MWs.
- o) Claims 20, 66-72, 74-85, 87, 88, 92 and 95 stand rejected under 35 U.S.C. § 112, first paragraph, written description, for not adequately describing the genus of the LIPG polypeptides.
- p) Claims 66-68 stand rejected under 35 U.S.C. § 112, first paragraph, written description, for not describing enhancers.
- q) Claims 20, 69-71 and 74-76 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.*
- r) Claims 20, 69-71, 74-84 and 95 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cooper *et al.* as evidenced by Gershenwald *et al.*

Conclusion

36. No claims are allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. Due to the new ground(s) of rejections set forth herein, the instant Office action is NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPUACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800